

§ 610.63

name identifying the product and symmetrically arranged with respect to other printing on the label.

(b) *Prominence.* The point size and typeface of the proper name shall be at least as prominent as the point size and typeface used in designating the trademark and trade name. The contrast in color value between the proper name and the background shall be at least as great as the color value between the trademark and trade name and the background. Typography, layout, contrast, and other printing features shall not be used in a manner that will affect adversely the prominence of the proper name.

(c) *Legible type.* All items required to be on the container label and package label shall be in legible type. "Legible type" is type of a size and character which can be read with ease when held in a good light and with normal vision.

§ 610.63 Divided manufacturing responsibility to be shown.

If two or more establishments participate in the manufacture of a product, the name, address, and license number of each must appear on the package label, and on the label of the container if capable of bearing a full label.

§ 610.64 Name and address of distributor.

The name and address of the distributor of a product may appear on the label provided that the name, address, and license number of the manufacturer also appears on the label and the name of the distributor is qualified by one of the following phrases: "Manufactured for _____", "Distributed by _____", "Manufactured by _____ for _____", "Manufactured for _____ by _____", "Distributor: _____", or "Marketed by _____". The qualifying phrases may be abbreviated.

[61 FR 57330, Nov. 6, 1996]

§ 610.65 Products for export.

Labels on packages or containers of products for export may be adapted to meet specific requirements of the regulations of the country to which the product is to be exported provided that in all such cases the minimum label re-

21 CFR Ch. I (4–1–99 Edition)

quirements prescribed in § 610.60 are observed.

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

Subpart A—Whole Blood

- Sec.
- 640.1 Whole Blood.
 - 640.2 General requirements.
 - 640.3 Suitability of donor.
 - 640.4 Collection of the blood.
 - 640.5 Testing the blood.
 - 640.6 Modifications of Whole Blood.

Subpart B—Red Blood Cells

- 640.10 Red Blood Cells.
- 640.11 General requirements.
- 640.12 Suitability of donor.
- 640.13 Collection of the blood.
- 640.14 Testing the blood.
- 640.15 Pilot samples.
- 640.16 Processing.
- 640.17 Modifications for specific products.

Subpart C—Platelets

- 640.20 Platelets.
- 640.21 Suitability of donors.
- 640.22 Collection of source material.
- 640.23 Testing the blood.
- 640.24 Processing.
- 640.25 General requirements.
- 640.27 Emergency provisions.

Subpart D—Plasma

- 640.30 Plasma.
- 640.31 Suitability of donors.
- 640.32 Collection of source material.
- 640.33 Testing the blood.
- 640.34 Processing.

Subpart E [Reserved]

Subpart F—Cryoprecipitate

- 640.50 Cryoprecipitate AHF.
- 640.51 Suitability of donors.
- 640.52 Collection of source material.
- 640.53 Testing the blood.
- 640.54 Processing.
- 640.55 U.S. Standard preparation.
- 640.56 Quality control test for potency.

Subpart G—Source Plasma

- 640.60 Source Plasma.
- 640.61 Informed consent.
- 640.62 Medical supervision.
- 640.63 Suitability of donor.
- 640.64 Collection of blood for Source Plasma.
- 640.65 Plasmapheresis.